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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,538	02/08/2002	Kevin B. Morton	NEOMTRX.004CP1	3962

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EXAMINER

Foreman, Jonathan M

ART UNIT	PAPER NUMBER
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3736

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DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/072,538

Applicant(s)

MORTON ET AL. *ad*

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,5,6. 6) ☐ Other:

## DETAILED ACTION

### *Information Disclosure Statement*

The information disclosure statements filed 5/14/02, 9/24/02 and 1/21/03 comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. They have been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1 – 5, 8, 15 – 25, 27 and 39 - 43 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 2,542,505 to Gascoigne.

In reference to claims 1 – 5, 8, 15 – 25, 27 and 39 - 43, Gascoigne discloses a control unit (Col. 3, lines 43 – 49); a patient interface unit (Figure 1); a control line (40 – 42) between the control unit and the patient interface unit; and a closed fluid circulation loop (Col. 3, lines 16 – 67), having a first component capable of removal carried by the control unit and a second component carried by the patient interface unit. The first component comprises a reservoir (54). The loop comprises a movable wall (18; Col. 2, line 25). The second component is an inflatable bladder (A, B). The control unit has a pump causing fluid circulation through the loop (Col. 3, lines 16 – 67). A heat exchange fluid is contained in the loop. Gascoigne discloses a support (Col. 1, line 56 – Col. 2, line

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5) for supporting the second component in contact with the patient. The support is adjustable in that it can be moved as desired. The patient interface has a disposable interface with a flexible polymeric membrane and a rigid support (Col. 2, lines 50 – 55).

3. Claims 21 and 27 – 29 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,034,006 to Hosoda et al.

In reference to claims 21 and 27 – 29, Hosoda et al. discloses a control unit (43); a patient interface unit (10); a control line (42) between the control unit and the patient interface unit; and a flow path between a first component carried by the control unit and a second component carried by the patient interface unit (Col. 4, lines 46 – 65). The second comprises at least 6 inflatable bladders.

4. Claims 21 and 23 - 26 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,941,859 to Lerman.

In reference to claims 21 and 23 - 26, Lerman discloses a control unit (28); a patient interface unit (10); a control line (24) between the control unit and the patient interface unit; and a flow path (24) between a first component carried by the control unit and a second component carried by the patient interface unit. The first component comprises a compressible reservoir removably carried by the control unit (Col. 4, line 67 – Col. 5, line 7). The flow path comprises a movable wall.

5. Claims 1 – 8, 15, 16, 21 – 23, 25 and 27 – 30 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,273,868 to Nordvik.

In reference to claims 1 – 8, 15, 16, 21 – 23, 25 and 27 – 30, Nordvik discloses a control unit (Col. 5, lines 41 - 50); a patient interface unit (1); a control line (17, 18) between the control unit and the patient interface unit; and a closed fluid circulation loop (Col. 6, lines 51 - 62), having a first component capable of removal carried by the control unit and a second component carried by the patient interface unit. The first component comprises a reservoir (19). The loop comprises a

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movable wall (Col. 6, lines 26 - 42). The second component is an inflatable bladder (6, 10). The inflatable bladder comprises at least 6 inflatable lobes. A heat exchange fluid is contained in the loop. The control unit has a pump causing fluid circulation through the loop (Col. 5, line 46).

6. Claims 21, 22, 27, 30 and 35 - 40 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,358,226 to Ryan.

In reference to claims 21, 22, 27, 30 and 35 - 40, Ryan discloses a control unit (Col. 4, lines 28 - 50); a patient interface unit (13); a control line (25, 43) between the control unit and the patient interface unit; and a flow path comprising a closed circulation loop between a first component carried by the control unit and a second component carried by the patient interface unit (Col. 6, lines 1 - 6). The second component comprises an inflatable bladder (Col. 3, lines 30 - 35). A heat exchange media is contained in the loop. Ryan discloses a heat source in the control unit (Col. 4, lines 35 - 38). The heat source is in removable thermal communication with the first component. Ryan discloses a pump in the control unit that applies compressive force to the flow path (Col. 4, lines 28 - 49). The patient interface unit has an adjustable support (Col. 3, lines 24 - 25).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 9 - 12 and 31 - 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6,273,868 to Nordvik.

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In regards to claims 9 – 12 and 31 – 34, Nordvik discloses the inflatable bladder comprising at least 3 inflatable lobes (6, 10). Yet, Nordvik fails to disclose the inflated width or thickness of each lobe. However, a change in the size of a prior art device is a design consideration within the skill of the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the size of the inflatable lobes as disclosed by Nordvik to be any size as desired.

9. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 2,542,505 to Gascoigne as applied to claim 1 above and further in view of U.S. Patent No. 6,358,226 to Ryan.

In reference to claims 13 and 14, Gascoigne discloses an intraductal fluid withdrawal system having a control unit (Col. 3, lines 43 – 49), but fails to disclose a heat source in the control unit. Ryan teaches an intraductal fluid withdrawal system having a heat source in the control unit (Col. 4, lines 27 – 49). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the control unit as disclosed by Gascoigne to include a heat source as taught by Ryan to increase the temperature of the mammary gland tissue to make milk withdrawal more comfortable (Abstract).

### ***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 6,663,587 to Silver et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

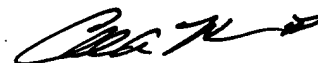
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-872-9306 for regular communications and (703)-872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.

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JMLF  
January 25, 2004



**CHARLES MARMOR  
PRIMARY EXAMINER**